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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/056,473	01/23/2002	Jude S. Sauer	INE-0002-C2	5120

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EXAMINER

BACHMAN, LINDSEY MICHELE

ART UNIT	PAPER NUMBER
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3734

NOTIFICATION DATE	DELIVERY MODE
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11/27/2009

ELECTRONIC

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Notice of the Office communication was sent electronically on above-indicated "Notification Date" to the following e-mail address(es):

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Office Action Summary	Application No. 10/056,473	Applicant(s) SAUER, JUDE S.	
	Examiner LINDSEY BACHMAN	Art Unit 3734	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 24 August 2009.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 5-10, 12, 13, 20, 21, 23-39, 42-45, 51-58, 63-73 and 80-88 is/are pending in the application.
- 4a) Of the above claim(s) 63-73 and 80-88 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 5-10, 12, 13, 20, 21, 23-39, 42-45 and 51-58 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
 - ☐ Certified copies of the priority documents have been received in Application No. _____.
 - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|---|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) |
| 2) <input type="checkbox"/> Notice of Draftperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____ |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

This Office Action is in response to Applicant's amendment filed 24 August 2009.

Response to Arguments

Applicant's arguments filed 24 August 2009 have been fully considered but they are not persuasive.

Regarding independent Claim 51, Applicant argues that Applicant's invention is more than merely providing separable components that were once integral, but instead provides a projections and grooves to better secure a ferrule holder on the tongue.

Applicant's arguments are not persuasive. It has been established in the courts that making objects separable is a matter of obviousness. For example, In *re Dulberg*, (289 F.2d 522, 523, 129 USPQ 348, 349 (CCPA 1961)) states that it would be obvious to make two parts separable if there is any reason to make them removable from one another. Applying this to the present case, it is old and well known to make parts separable from a medical device in order to specific parts of the device or to sterilize the device for a future use.

Regarding Applicant's arguments for Claim 12, in which Applicant states that channel 40 of Sauer'666 is not a guide wire tube, as stated by the Examiner, but is instead a needle channel. This argument is not persuasive because Applicant has claimed any thing that differentiates the claimed guide wire channel from channel 40 of Sauer'666.

Claim Rejections - 35 USC § 102

The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

Claims 12, 13, 53, 54, 56 and 58 are rejected under 35 U.S.C. 102(b) as being anticipated by Sauer et al. (US Patent 5,431,666).

Claim 12, 13: Sauer discloses a device that contains a tongue member (37b) having a distal section insertable into a wound. The device also contains a face (distal face of grooves 40, 42 next to element 44. This face can be seen in Figures 2 and 12-14 - it is unlabeled) separated from the tongue by a gap (44). The device further contains a guidewire tube (40) disposed through an elongate body assembly (37). The distal end of the guidewire tube is next to an opening in the tongue member (the opening in 37b is unlabeled, but it is clear from the drawings that there is an opening used to accommodate elements 16, 18).

Claim 53, 54: Sauer discloses a tip for a surgical apparatus that contains a window (44), a first wall (distal face of grooves 40, 42 next to element 44. This face can be seen in Figures 2 and 12-14 - it is unlabeled) at an angle to the longitudinal axis and a second wall (proximal face of 37b) having a tongue (37b) with an opening (unlabeled but used to hold ferrules 16, 18). The base of the tongue forms the bottom portion of the window (see Figure 2).

Claim 55, 56: The proximal end of the tongue forms a T-shaped extension (the two needle holders 40, 42 are formed as grooves in element 37 - this creates a T-shaped extension as shown in Figure 2).

Claim 53 (alternate rejection), 58: Sauer discloses a device that contains a window (opening of region 34 in Figure 2), a first wall (face of element 32), a second wall (proximal face of element 30b-shown in Figure 2) and a tongue (34) that forms a bottom portion of the window. The tongue contains a longitudinal opening (element 30 is a tube) with an opening at the distal end that is proximal to the distal end of the tip (opening at 30b is used to accommodate element 37b).

Claim Rejections - 35 USC § 103

The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

Claims 51 and 5-10, 20, 21, 23-39, 42-45 are rejected under 35 U.S.C. 103(a) as being unpatentable over Sauer'666.

Claim 51, 52: Sauer teaches a device that contains a window (opening at 44); a first wall (distal face of grooves 40, 42 next to element 44. This face can be seen in Figures 2 and 12-14 - it is unlabeled); a second wall (proximal face of 37b) having a ferrule holder (opening in 37b holds ferrules 16, 18 as shown in Figure 2) and a tongue (44) extending between the first and second walls.

Sauer'666 discloses the claimed invention except Sauer'666 does not teach that the ferrule holder is separable from the tongue. The Sauer'666 device would work in the same way if the ferrule holder were separable from the tongue. It would have been obvious to one having ordinary skill in the art at the time the invention to make the ferrule holder separable from the tongue, since it has been

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held that constructing a formerly integral structure in various elements involves only routine skill in the art. *Nerwin v. Erlichman*, 168 USPQ 177, 179. and MPEP 2144.04. Also, see further arguments above regarding *In re Dulberg*, (289 F.2d 522, 523, 129 USPQ 348, 349 (CCPA 1961)). The case states states that it would be obvious to make two parts separable if there is any reason to make them removable from one another. Applying this to the present case, it is old and well known to make parts separable from a medical device in order to specific parts of the device or to sterilize the device for a future use.

Claim 5, 6, 7, 8: Sauer further teaches that the device contains an elongate body assembly (37) connecting a body portion (12) to the tongue member (44). The device further contains two elongate needles (36, 38) positioned within the elongate body assembly (in grooves 40, 42) (column 5, lines 20-36). The first and second needles is movable by a first and second levers (70, 72 respectively) (column 6, lines 38-44).

Claim 9: Sauer teaches a body portion (12) having first and second levers (160, 162) pivotally secured to the body portion (via element 164, see Figures 5-6) connected with the first and second needles (column 8, lines 4-14). Sauer does not disclose the use of multiple colors to identify which lever is interacting with which needle. However, the concept of color-coding is well known in the art. Patentability cannot be predicated on color-coding a surgical device. The color-coding so as to identify which needle each handle is operating would have been entirely obvious. Further, applicant has not shown any functional criticality for

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color-coding the levers. The device will perform the same way regardless of the color.

Claim 10: Sauer teaches a body portion (12) having first and second levers (160, 162) pivotally secured to the body portion (via 164, see Figures 5-6). The first and second levers are mounted to the distal end of the body portion (see Figures 1, 5 and 6).

Claim 20, 21: Sauer teaches a body portion (12); a tubular portion (170) attached to the distal end of the body; and a lever (172) having a distal end operatively coupled to the distal end of the body portion. The lever is parallel to the longitudinal axis in the closed position (see Figure 5).

Claim 23: Sauer teaches a body portion (12); a tubular portion (170) attached to the distal end of the body; and a lever (172) having a distal end operatively coupled to the distal end of the body portion. The device further contains a first and second link (36a, 38a) connected to the lever at one end and to first and second slidable member (70 and 72) at the other end of the link. The slidable members move within the body portion (see Figures 5 and 6).

Claim 24: Movement of the lever towards the proximal end of the body portion causes one slidable member to move towards the distal end of the body portion and the other slidable member to move away from the distal end of the body portion (column 8, lines 26-58).

Claim 25, 26: Sauer discloses a drive block (106) in which the slidable member cooperates with the drive block to move the drive block with the slidable member (column 11, lines 12-30).

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Claim 27, 29: The drive block is biased with a spring (118, 120) (column 7, lines 23-28).

Claim 28: The drive block contains a longitudinal opening (see Figure 4 or 8).

Claim 23 (alternate rejection), 39: Sauer teaches a body portion (12); a tubular portion (170) attached to the distal end of the body; and first and second levers (160, 162) having a distal end operatively coupled to the distal end of the body portion. The device further contains first and second link (36a, 38a) connected to the lever at one end and to first and second slidable member (70 and 72) at the other end of the link. The slidable members move within the body portion (see Figures 5 and 6).

Claim 30, 31, 33, 34, 35, 36, 37: Movement of the lever towards the proximal end of the body portion causes one slidable member to move towards the distal end of the body portion and the other slidable member to move away from the distal end of the body portion (column 8, lines 26-58). The slidable members (70, 72) are needle drivers.

Claim 32: The needles are disposed within the tubular portion (Figures 10, 11).

Claim 42, 43, 44, 45: Sauer teaches a body portion (12), a tubular portion (30) and first and second levers (160, 162) pivotally secured to the body portion (via element 164, see Figures 5-6) connected with the first and second needles (column 8, lines 4-14). Regarding claim 45, Sauer does not disclose the use of multiple colors to identify which lever is interacting with which needle. However,

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the concept of color-coding is well known in the art. Patentability cannot be predicated on color-coding a surgical device. The color-coding so as to identify which needle each handle is operating would have been entirely obvious. Further, applicant has not shown any functional criticality for color-coding the levers. The device will perform the same way regardless of the color.

Claim 57 is rejected under 35 U.S.C. 103(a) as being unpatentable over Sauer'666.

Claim 57: Sauer'666 discloses the claimed invention except Sauer'666 does not teach that the ferrule holder is separable from the tongue. It would have been obvious to one having ordinary skill in the art at the time the invention to make the ferrule holder separable from the tongue, since it has been held that constructing a formerly integral structure in various elements involves only routine skill in the art. *Nerwin v. Erlichman*, 168 USPQ 177, 179. and MPEP 2144.04.

Claim 57 is rejected under 35 U.S.C. 103(a) as being unpatentable over Sauer'666.

Claim 57: Sauer'666 discloses the claimed invention except Sauer'666 does not teach that the ferrule holder is separable from the tongue. It would have been obvious to one having ordinary skill in the art at the time the invention to make the ferrule holder separable from the tongue, since it has been held that constructing a formerly integral structure in various elements involves only routine skill in the art. *Nerwin v. Erlichman*, 168 USPQ 177, 179. and MPEP 2144.04.

Conclusion

THIS ACTION IS MADE FINAL. Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire **THREE MONTHS** from the mailing date of this action. In the event a first reply is filed within **TWO MONTHS** of the mailing date of this final action and the advisory action is not mailed until after the end of the **THREE-MONTH** shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than **SIX MONTHS** from the mailing date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to LINDSEY BACHMAN whose telephone number is (571)272-6208. The examiner can normally be reached on Monday to Thursday 7:30 am to 5 pm, and alternating Fridays.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Todd Manahan can be reached on 571-272-4713. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

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Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Kevin T. Truong/
Primary Examiner, Art Unit 3734

/L. B./
Examiner, Art Unit 3734